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EXAMINER  
DAVIS, DEBORAH A

ART UNIT 1641  
PAPER NUMBER

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/638,102

Applicant(s)

SCHWARTZ, DAVID C.

Examiner

Deborah A Davis

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-14 and 34-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35 is/are allowed.
- 6) ☒ Claim(s) 1,2,5-14,34 and 36-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicants' response to the Office Action mailed on March 23, 2004 has been acknowledged. Currently, claims 1-2, 5-7, 9, 34, 36-40 are pending and under consideration. Claims 41 and 42 are newly added claims.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 37-39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "chemically reactive substances are exposed on the sides of the filaments" in newly added claim 37, line 5 is not supported by the instant specification. Applicant is invited to show support for this limitation.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

a. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 5, 6, 7, 9, 34, 36-38, 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al (USP# 4,867,946) in view of Adams et al (USP#6,156,494)

Gross et al anticipates the instant claims by teaching a device for evaluating test strips used to screen a variety of different samples. The test strips contain several test sections where the reagents are placed for testing (col. 1, 2<sup>nd</sup> para and see Figure 2). The device has a platform and a holder to support the test strips (col. 2, see claim 1) in a parallel relationship in which the test strips are perpendicular to the holder (see Figure 2). The test strip has test sections spaced along the strips to allow samples to be deposited (see Figure 2). The limitation "support frame holding the plurality of different filaments for mutual exposure to a material to be screened" as recited in claims 1, 34, and 36 will not be given patentable weight because it is intended use. With respect to the recitation of a "semi-custom array for chemical screening" in the preamble has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951). With respect to the newly added limitation of claim 42 that recites "semi-customizable strips", according to the definition on page 10, lines 1-17 of the instant specification, examiner maintains that the prior art still apply.

Gross et al differ in the instant invention because it does not specifically point out that the organic compounds used are from the groups of oligonucleotides and peptides and that the substrate is of glass fiber.

However, Adams et al teaches methods for utilizing optical fibers as a solid support for the assembly of combinatorial compounds. The optical fibers are used to direct light, heat or a combination thereof (see abstract). Adams et al discloses that optical fibers can be used to screen organic compounds, utilizing them in combinatorial libraries that include oligomeric and small molecules (column 3, lines 65-67 and column 4, lines 1-9).

It would have been obvious to one of ordinary skill in the art to modify the teaching of Gross et al to include the screening of organic material such as peptides and oligonucleotides on glass fibers as taught by Adams et al to direct heat and light or a combination thereof to compounds on the surface of the fibers (see abstract) so compounds can be screened for binding activity.

6. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Bensten et al (USP#6,372,895).

The teachings of Gross et al are set forth above and differ in the instant invention because it does not teach strips that include a marker selected from the group of printing and fluorescent material nor the use of organic compounds.

However, Bentsen et al teaches in one of his embodiments an apparatus that uses a test strip that contains a printed barcode wherein the printed material on the

barcode has an enzyme or spore. The strip is further sterilized and dipped into a buffer solution containing Fluorescence Enzyme Substrate (FES). If enzyme activity is present, the printed pattern will become detectable (col. 20, lines 66-67 and col. 21, 1<sup>st</sup> para).

It would have been obvious to one of ordinary skill in the art to have incorporate the printed barcode as taught by Bentsen et al into the strips of Gross et al to detect enzyme activity.

7. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Zuk et al (4,281,061).

Claim 41 is drawn to a chemical screening kit which examiner still maintains applicant has not shown support for this limitation. The teaching of Gross et al art set forth above and teach the limitations of the instant claims but is silent with respect to a kit.

However, Zuk et al. teaches that "as a matter of convenience the reagents can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (column 22, lines 63-66).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the reagents and other materials as taught by Gross et al and format them into a kit because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit along with

other materials. Further, the reagents in a kit are available in pre-measured amounts which eliminates the variability that can occur when performing the assay.

### **Allowable Subject Matter**

8. Claims 8, 35 and 39 are allowed.
9. Claims 8 and 39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

10. Applicant traverses the written description requirement applied to claim 37, line 5 "chemically reactive substances are exposed on the sides of the filaments" and maintains that it has support in the specification on page 4, lines 16-21. Applicant further recites case law that states the specification need not describe the claimed subject matter in exactly the same terms as used in the claims if one skilled in the art would recognize upon reading the new language reflects what the disclosure shows has been invented. This argument is noted but not found persuasive.

In response to applicants' argument, the section of the specification that the examiner was directed to (page 4, lines 16-21), did not describe "chemically reactive

substances are exposed on the sides of the filaments", but only described substances exposed on the surface of the filaments which the examiner interprets to be substances exposed on top of the filaments along its length. Further, it is the examiner's view that one of ordinary skill in the art would also draw the same conclusion given the support in the specification.

11. Applicant argument that Gross teaches the use of large paper strips to detect substances present in urine. Unlike the invention in the present application, the test strips of Gross are exactly the same. There is no customization of the urine test strips and there is not variation of the test sections between each urine test strip in Gross as there are in the invention of the present application. This argument is not found persuasive.

In response to applicants' argument, the reference of Gross uses different reagents in test sections along the length of the strips which are then dipped in a urine sample to screen for a variety of compounds such as bilirubin, urobilinogen, ketone bodies, protein, nitrite and other (column 1, lines 10-17).

12. Applicants' argument that the reference of Adams teach the use of optical fibers to synthesize and screen combinatorial libraries of oligomeric and non-oligomeric compounds are not found persuasive because the claim consist of comprising language and therefore does not exclude the use of non-oligomeric compounds.



13. Applicants' argument that the reference of Adams teaches that its optical fibers are bundled side by side into an imaging fiber/optical sensor and that it is apparent from the description of the invention and its use, and from the figures, that the chemical compounds are placed on the ends, not the sides of the strips are not found persuasive. Applicant further argues that the references alone or in combination teach the kit claim of 41. This argument is not found persuasive.

In response to applicants' arguments, the reference of Adams teaches an array of compounds on the regions along the optical fibers not placed at the ends as applicant suggests (column 5, lines 1-65) and taught throughout the reference. The optical fibers are side by side in parallel, which meet the instant claims.

14. Applicant's argument that there is not suggestion to combine because the reference of Adams teaches away from the combination by describing a system of synthesis of multiple compounds in place on a pre-assembled bundle and that the two inventions would be ill-served by the apparatus of the other. This argument is not found persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

*Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the reference of Adams was relied on for its teaching of optical fibers and organic compounds used on the fibers. The reference of Adams does not teach away from the combination because it includes other embodiments such as synthesis of multiple compounds in place on a pre-assembled bundle as applicant suggests. Adams teaches that optical fibers can be used to screen organic compounds, utilizing them in combinatorial libraries that include oligomeric compounds that read on the instant claims.

15. Applicant argument that a kit claim has been reintroduced as claim 41, and was previously rejected by the examiner because it was believed that there was not support for the phrase "chemical screening kit" (paper 13, paragraph 2), eventhough applicant maintains there was support in the specification at page 10, lines 7-17. Applicant, to further expedite prosecution, amended the preamble to "semi-custom array for chemical screening" which was not given patentable weight by the examiner. This argument is not found persuasive.

In response to applicants' argument, examiner found no support for a kit in the specification and therefore a new matter rejection was proper (see paper #13, paragraph 2). Although the kit claims were considered new matter for lack of support in the specification, it would have been obvious to one of ordinary skill in the art to format reagents and other articles into a kit, which has been addressed the above rejection. Although the preamble was amended to read "semi-custom array", whether the

preamble was given patentable weight or was not given patentable weight, the prior art still met the limitations of the claims.

16. Applicant argument that examiner didn't allow patentable weight for the limitation of "support frame holding the plurality of different filaments for the mutual exposure to be screened," in claims 1, 34, and 36 because it is a statement of intended use is incorrect because this limitation defines how the strips are held, whether or not screening ultimately occurs. This argument is not found persuasive.

In response to applicant's argument, it is noted, however, the examiner **has** given patentable weight to the support frame holding the plurality of different filaments, but no patentable weight was given to: "for the mutual exposure to be screened". Examiner only repeated the complete sentence for clarity. With respect to the case law cited "In re Venezia, 530 F.2d 956 (C.C.P.A. 1976)" and MPEP 2173.05(g) that addresses proper interpretation of a "kit claim" is noted. However, applicant was given a new matter rejection for lack of support, not improper kit claims.

17. Applicant argument that the reference of Bensten does not teach the use of a bar code to identify the filaments but only uses the bar code to identify how the filaments react in a given experiment and therefore not combinable with the reference of Gross is not found persuasive.

In response to applicants' argument, the reference of Bensten teaches the use of a barcode onto a test strip. Although the reference does not specifically recite that the

barcode is used to distinguish test strips, it is well known in the art that a function of a barcode on a test strip is used for identification purposes.

### ***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

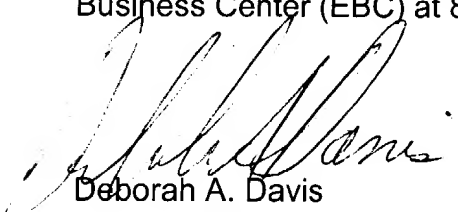
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

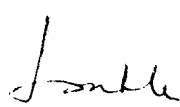
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah A. Davis  
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October 6, 2004



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10/15/04